

Notice of Allowability

Application No.

10/664,775

Examiner

Anand U. Desai, Ph.D.

Applicant(s)

SIMESSEN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 29, 2004.
2. ☒ The allowed claim(s) is/are 3-36 and 38-41.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 20050307.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date May 28, 2004 Pg.1
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20050303&20050307.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on November 29, 2004. Claims 1, 2, and 37 have been cancelled. Claims 3-36, and 38-41 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claims 3, 4, 15, 16-27, and 30-41 under 35 U.S.C. 112, 2nd paragraph is withdrawn.

3. The rejection of claims 1-27, and 29-40 under 35 U.S.C. 1st paragraph, as failing to comply with the written description requirement is withdrawn.

4. The rejection of claims 1-27 under 35 U.S.C. 1st paragraph, scope of enablement is withdrawn based on amendment to the claims.

5. The rejection of claims 16-18 under 35 U.S.C. 102(b) as being anticipated by Delcuve (U.S. Patent 5,888,774) is withdrawn based on Applicants amendment.

6. The rejection of claims 1-5, 15-18, and 36 under 35 U.S.C. 103(a) as being unpatentable over Delcuve (U.S. Patent 5,888,774) in view of Hagen et al. (U.S. Patent 4,784,950) is withdrawn based on Applicants amendment.

Maintenance of Objections

Drawings

7. The drawings are objected to because figure 10 has the brief description of the drawing below the drawing. Suggest placing the legend in the brief description of the drawing section of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

EXAMINER'S AMENDMENT

8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Len Smith on March 7, 2005.

Examiner's Amendment to the Claims:

Claim 4 (Currently Amended) The method of claim 3, wherein the nucleic acid molecule comprises two S/MAR elements selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5. ~~(i) SEQ ID NO: 1 or SEQ ID NO: 2, (ii) functional fragments of SEQ ID NO: 1 or SEQ ID NO: 2, and (iii) sequences that are at least about 70% identical to SEQ ID NO: 1 or SEQ ID NO: 2.~~

Claim 15 (Currently Amended) The method of claim 3, wherein the at least one S/MAR element is located less than ~~about~~ 10 kb from the Factor VII or Factor VII-related polypeptide-encoding sequence.

Claim 16 (Currently Amended) A method for producing a protein comprising (a) transfecting a mammalian cell with a nucleic acid molecule comprising (I) a sequence encoding

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the protein and (II) at least one scaffold/matrix attachment region (S/MAR) element comprising SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, or SEQ ID NO: 5; ~~(i) SEQ ID NO: 1 or SEQ ID NO: 2, (ii) a functional fragment of SEQ ID NO: 1 or SEQ ID NO: 2, or (iii) a sequence that is at least about 70% identical to SEQ ID NO: 1 or SEQ ID NO: 2;~~ (b) culturing the transfected cell under conditions suitable for expression of the ~~polypeptide or~~ protein; and (c) isolating the expressed ~~polypeptide or~~ protein.

Claim 17 (Currently Amended) The method of claim 16, wherein the nucleic acid molecule comprises two S/MAR elements selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5.

Claim 28 (Currently Amended) An isolated DNA molecule comprising one or more S/MAR elements that comprise a sequence selected from the group consisting of ~~SEQ ID NOs: 1-5~~ SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5.

Claim 30 (Currently Amended) The isolated DNA molecule of claim 29, wherein the protein or polypeptide-encoding sequence is located less than ~~about~~ 10 kb from the one or more S/MAR elements.

Claim 36 (Currently Amended) A vector construct comprising a nucleic acid molecule comprising (a) a sequence encoding Factor VII or a Factor VII-related polypeptide operably linked to one or more expression control elements and (b) one or more S/MAR elements selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5 ~~SEQ ID NOs: 1-5.~~

Claim 39 (Currently Amended) A vector construct comprising a nucleic acid molecule that comprises (a) a sequence encoding a polypeptide or protein operably linked to one or more

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expression control elements and (b) at least one S/MAR element comprising a sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5 ~~SEQ ID NOs: 1-5~~.

Claim 41 (Currently Amended) An isolated DNA molecule consisting essentially of one or more sequences selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5 ~~SEQ ID NOs: 1-5~~.

Conclusion

10. Claims 3-36, and 38-41 are allowable.

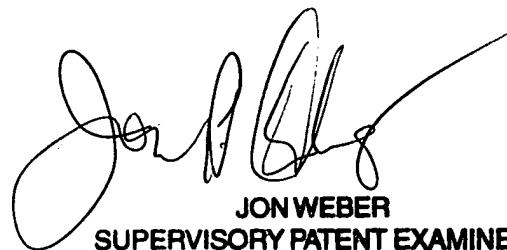
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 7, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER